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Add the following:

▲Coptis Species Rhizome

DEFINITION

Coptis Species Rhizome consists of the dried rhizome of *Coptis chinensis* Franch., *Coptis deltoidea* C.Y.Cheng & P.K.Hsiao, or *Coptis teeta* Wall. (Family *Ranunculaceae*), with roots removed, collected in autumn. It contains NLT 9.0% and NMT 20% of total quaternary protoberberine alkaloids calculated on the dried basis as the sum of columbamine ($C_{20}H_{20}NO_4^+$), jatrorrhizine ($C_{20}H_{20}NO_4^+$), epiberberine ($C_{20}H_{18}NO_4^+$), coptisine ($C_{19}H_{14}NO_4^+$), palmatine ($C_{21}H_{22}NO_4^+$), and berberine ($C_{20}H_{18}NO_4^+$); and NLT 5.0% and NMT 15% of berberine on the dried basis.

IDENTIFICATION

• A. HPTLC FOR ARTICLES OF BOTANICAL ORIGIN (203)

Standard solution A: 0.025 mg/mL of [USP Coptisine Chloride RS](#) and 0.05 mg/mL of [USP Berberine Chloride RS](#) in [methanol](#). Sonicate to dissolve.

Standard solution B: 1 mg/mL of [USP Coptis chinensis Rhizome Dry Extract RS](#) in [methanol](#). Sonicate for 15 min, centrifuge, and use the supernatant.

Sample solution: 10 mg/mL of finely powdered *Coptis* Species Rhizome in [methanol](#). Sonicate for 15 min, centrifuge, and use the supernatant.

Chromatographic system

Adsorbent: [Chromatographic silica gel F₂₅₄ mixture](#)

Application volume: 5 µL, as 8-mm bands

Relative humidity: Condition the plate to a relative humidity of about 33% using a suitable device.

Temperature: About 25°

Developing solvent system: [Toluene](#), [ethyl acetate](#), [isopropyl alcohol](#), [methanol](#), and [water](#) (20:10:5:5:1)

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Apply the *Samples* as bands and dry in air. Develop in a chamber that has been saturated without filter paper for 20 min with developing solvent in the front trough and 25 mL of 32% [ammonia](#) in the rear trough. Remove the plate from the chamber, and dry in a vacuum hood. Examine under UV light at 365–366 nm.

System suitability

Samples: *Standard solution A* and *Standard solution B*

Suitability requirements: *Standard solution A* exhibits, from the bottom to the top of the chromatogram, a green band due to berberine and a yellow band due to coptisine. *Standard solution B* exhibits, from the bottom to the top of the chromatogram, two close faint dark-green bands in the first quarter due to columbamine and jatrorrhizine; two green bands—one corresponding in R_f and color to berberine in *Standard solution A*, and the other below berberine due to palmatine; and two yellow bands—one corresponding in R_f and color to coptisine in *Standard solution A*, and the other (between berberine and coptisine) due to epiberberine.

Acceptance criteria: The *Sample solution* exhibits, from the bottom to the top of the chromatogram, two close faint dark-green bands in the first quarter corresponding in R_f and color to columbamine and jatrorrhizine in *Standard solution B*; two green bands—one corresponding in R_f and color to berberine in *Standard solution A* and *Standard solution B*, and the other below berberine corresponding in R_f and color to palmatine in *Standard solution B*; two yellow bands—one corresponding to coptisine in *Standard solution A* and *Standard solution B*, and the other (between berberine and coptisine) corresponding in R_f and color to epiberberine in *Standard solution B*. Relative to coptisine, the intensity of the epiberberine band is similar in *C. chinensis*, weaker in *C. deltoidea*, and more faint in *C. teeta*.

• B. HPLC

Analysis: Proceed as directed in the test for *Content of Quaternary Protoberberine Alkaloids*.

Acceptance criteria: The *Sample solution* exhibits the most intense peak corresponding to the retention time of berberine, and the second most intense peak corresponding to the retention time of coptisine in *Standard solution A* and *Standard solution B*. The *Sample solution* also exhibits a peak between berberine and coptisine that has a lower intensity than coptisine and is due to palmatine. Three adjacent minor peaks ahead of coptisine correspond to columbamine, jatrorrhizine, and epiberberine in *Standard solution B*. The relative intensity of columbamine, jatrorrhizine, and epiberberine peaks varies with the species: *C. chinensis* shows epiberberine as the most intense peak; *C. deltoidea* shows jatrorrhizine as the most intense peak with epiberberine having a peak similar in intensity to columbamine; *C. teeta* shows jatrorrhizine as the most intense peak with epiberberine having a very minor or nondetectable peak. No other peak in the chromatogram

between the peaks of columbamine and berberine is more intense than the peak corresponding to columbamine. The relative content to total quaternary protoberberine alkaloids content is about 1/2 or more for berberine; about 1/5–1/7 for coptisine; and about 1/5–1/10 for the sum content of the three minor peaks. The content ratios of each alkaloid relative to berberine are within the ranges listed in [Table 1](#).

Table 1

Alkaloid	Content Ratio Relative to Berberine		
	<i>C. chinensis</i>	<i>C. deltoidea</i>	<i>C. teeta</i>
Columbamine	0.06–0.11	0.03–0.08	0.01–0.03
Jatrorrhizine	0.05–0.11	0.12–0.34	0.08–0.22
Epiberberine	0.13–0.24	0.02–0.09	~0
Coptisine	0.22–0.46	0.16–0.48	0.1–0.3
Palmatine	0.18–0.32	0.10–0.22	0.03–0.08
Berberine	1.0	1.0	1.0

COMPOSITION

• CONTENT OF QUATERNARY PROTOBERBERINE ALKALOIDS

Mobile phase: A mixture of [water](#) containing 0.05 mol/L of [monobasic potassium phosphate](#) and [acetonitrile](#) (64:36). Add 25.24 g/L of [sodium 1-heptanesulfonate](#), and adjust with [phosphoric acid](#) to a pH of 4.0.

Solvent 1: [Methanol](#) and [water](#) (7:3)

Solvent 2: 1% [hydrochloric acid](#) in [methanol](#)

Standard stock solution: 0.40 mg/mL of [USP Berberine Chloride RS](#) and 0.20 mg/mL of [USP Coptisine Chloride RS](#) in *Solvent 1*

Standard solution A: 0.04 mg/mL of [USP Berberine Chloride RS](#) and 0.02 mg/mL of [USP Coptisine Chloride RS](#) from *Standard stock solution* diluted with *Solvent 1*.

Standard solution B: About 0.5 mg/mL of [USP Coptis chinensis Rhizome Dry Extract RS](#) prepared as follows. Transfer a weighed amount of [USP Coptis chinensis Rhizome Dry Extract RS](#) into a suitable volumetric flask, add *Solvent 2* to 70% of the final volume, and sonicate for 30 min. Cool to room temperature, add water to the volume, and mix well. Before injection, pass through a suitable membrane filter of 0.45-µm or finer pore size.

Sample solution: Transfer about 40 mg of finely powdered *Coptis* Species Rhizome, accurately weighed, into a 50-mL volumetric flask, add 40 mL of *Solvent 2*, and sonicate for 30 min. Cool to room temperature, add water to the volume, and mix well. Before injection, pass through a suitable membrane filter of 0.45-µm or finer pore size and discard the first portion of the filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), *System Suitability*.)

Mode: LC

Detector: UV 345 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L1](#)

Column temperature: 25°

Flow rate: 0.5 mL/min

Injection volume: 10 µL

System suitability

Samples: *Standard solution A* and *Standard solution B*

Suitability requirements

Resolution: NLT 1.3 between columbamine and jatrorrhizine; NLT 1.3 between jatrorrhizine and epiberberine, *Standard solution B*

Tailing factor: NMT 1.5 for coptisine and berberine, *Standard solution A*

Relative standard deviation: NMT 2.0% for berberine and coptisine in repeated injections, *Standard solution A*

Chromatogram similarity: The chromatogram of *Standard solution B* is similar to the reference chromatogram provided with the lot of [USP Coptis chinensis Rhizome Dry Extract RS](#) being used.

Analysis

Samples: *Standard solution A*, *Standard solution B*, and *Sample solution*

Using the chromatograms of *Standard solution A*, *Standard solution B*, and the reference chromatogram provided with the lot of [USP Coptis chinensis Rhizome Dry Extract RS](#) being used, identify the peaks corresponding to columbamine, jatrorrhizine, epiberberine, coptisine, palmatine, and berberine in the *Sample solution*.

Calculate separately the percentages of berberine, jatrorrhizine, columbamine, and palmatine against berberine in [USP Berberine Chloride RS](#); also calculate separately the percentages of coptisine and epiberberine against coptisine in [USP Coptisine Chloride RS](#). If the relative response factors for berberine, jatrorrhizine, columbamine, and palmatine are similar, thus all of these alkaloids can be